Tank Mixture Label Language

CropLife America (CLA) appreciates the continued efforts of the U.S. Environmental Protection Agency (EPA or the Agency) to respond to the needs of growers and pesticide applicators who face multiple pests and pest scenarios. As tank mixtures can be an important tool in pest control, and in the management of pest resistance, CLA requests that EPA Office of Pesticide Program (OPP) explicitly clarify in the Label Review Manual for registrants and Agency reviewers alike that label recommendations regarding tank mixtures may specify product brand names, active ingredients, use rates, and/or other details for tank mix partner products, to ensure that customers know how to use the products effectively and safely in combination.

CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners.

The benefits of tank mixing are well-recognized, including by EPA. Tank mixes broaden the spectrum of weed species control; can be used effectively to delay the development of herbicide resistant weeds; and improve crop safety at listed use rates. At the January 2018 Weed Science Society of America symposium, EPA OPP Director Rick Keigwin enumerated on these benefits and reported on the widespread use of tank mixing around the United States. Despite this recognition, our members have shared with us that OPP reviewers have been inconsistent in approving tank mixture recommendations or have not allowed complete information to appear on the label, leading to potential confusion among growers and ultimately, potentially less use of this important crop protection strategy.

Before recommending tank mixtures on a product label, the registrant evaluates them for performance (what application rates should be used to achieve desired level of crop protection), safety to the crop, and chemical compatibility, through testing and field experience. The registrant's recommendations are valuable to growers and applicators, so that they know how to address their crop protection needs properly and ensure regulatory compliance. As set forth below, CLA understands that some OPP reviewers may be inconsistently applying OPP guidance regarding tank mix labeling, denying growers and other applicants the benefit of the registrant recommendations.

A. Inconsistent Directions Regarding Tank Mix Labeling

In accordance with the label requirements set out in 40 CFR 156.10, the EPA Label Review Manual (LRM) allows for tank mixtures.¹ "EPA will not accept or require the prohibition against the use of one pesticide product with another product unless the statement is necessary to protect human health or the environment …" Recommending specific products does not

¹ See EPA OPP Label Review Manual, Chapter 11, Section IX.C, p. 11-24 (2014).

preclude growers from mixing other products as they see fit, as indicated in the LRM. However, some reviewers have not allowed registrants to provide complete tank mixture information on the label and have erroneously cited the LRM as a justification. Over the past year, certain registrants have been told by reviewers that the label may not specify product brand names or use rates for tank mix partners. Additionally, several EPA reviewers have required changes that could lead to greater confusion and opportunity for error for growers and pesticide applicators.

1. Brand Names

Registrants have been directed to refer to the common names of active ingredients when developing tank mix instructions. However, growers and applicators are more familiar with trade names of pesticide products, rather than with the common names of active ingredients. Also, different products containing the same active ingredient can differ in concentration of that active ingredient. Requiring the omission of brand names from tank mix recommendations increases the confusion for growers in finding the right product to use. Furthermore, two products with the same Al and same registered uses can differ in formulation and inert ingredients, affecting compatibility of tank mixes differently.

Some reviewers have instructed registrants to include the EPA registration number of a tank mix partner rather than the brand name. Specifying the EPA registration number of a tank mix partner product on the label has its drawbacks. With corporate mergers, acquisitions, and product divestitures, the EPA registration number may be more likely to change than the product brand name, which will probably be retained through such changes. Thus, the product brand name is most consistent overall for communicating the essential information to the applicator, who will be applying a tank mix.

2. Use Rates

Some reviewers, citing the LRM, require label statements requiring users to follow the most restrictive directions for use and precautionary statements of each product in the tank mixture, but do not allow the registrant to provide specific directions for tank mixing. If the use rates for tank mix partners are omitted, the pesticide applicator has a greater burden to calculate use rates and amount of product from percent active ingredient on the partner label, with greater opportunity for error.

Further, if labels of *both* products for a two-way tank mix are prohibited from including recommended use rates for tank mix partners, the applicator will have more difficulty in determining the appropriate use rates for the mixture.

Following the use rates from the tank mix partner label in all cases, without further clarification, can create problems. For example:

Using the full labeled rate of two herbicides together can, in some situations, result in
unacceptable crop injury. Herbicide product labels provide a range of use rates for control
of different susceptible weeds. Tank mixing with another herbicide must provide
acceptable weed control from the perspective of resistance management, while avoiding
unacceptable crop injury.

Omitting use rates for tank mix partners adds to the burden of the applicator to determine
the appropriate use rate and increases the opportunity for error. Errors in calculating use
rates and in product selection can increase risk of crop loss for growers and will increase
liability for registrants.

Additionally, some reviewers have asked that the active ingredient use rate (e.g., lb ai per acre) be mentioned in parentheses after each mention of a product use rate (e.g., pints per acre). This extra detail adds distractive clutter to the label, with little benefit to the applicator. Some labels include a table in a strategic location comparing product use rates and AI use rates for all tank mix partner products. This practice could be adopted more broadly for labels with many tank mix recommendations.

B. CLA Proposes LRM Revisions

The revisions proposed below are examples of language that could be used. CLA would like the opportunity to work with EPA to develop language more fully.

LRM language revisions would allow specific brand names and use rates for tank mix partners. The Tank Mixing Statement² could benefit from revision to read:

"A tank mixture not specifically mentioned or prohibited on this label can also be used, so long as the applicator complies with the most restrictive directions and limitations on labels of all products used in the mixture."

Such a statement could be included a single time on the label and be referenced as needed (rather than repeated) with the instructions for each individual tank mix. Repeating this statement every time "tank mix" is mentioned will increase the label length, complexity, review time, and printing costs. This text change would avoid conflict with the the variety of statements that now can occur on product labels under the headings of **Tank Mixtures** and **Physical Compatibility**.

Conclusion

CLA and its members would like to work with the Agency to develop procedures that reduce the effort necessary in the label review process to assure that tank mix recommendations are current, valid, and compatible with respect to product names and use rates, across the products and labels involved. Thank you for taking the time to review our concerns, and we look forward to working with you to resolve this issue.

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² See EPA OPP <u>Label Review Manual</u>, Chapter 11, Section IX.C, p. 11-23 (2014).